

REMARKS

The Final Office Action mailed April 30, 2009, has been received and reviewed. Currently pending in the application are Claims 1, 3-25, 31, 32, 34-38, and 40-43, of which Claims 1, 14, 21, and 31 are independent. No new matter has been introduced by this Response. The Applicant respectfully traverses the rejections and requests reconsideration.

Claim Rejections Under 35 USC § 103

Claims 1, 3-8, 13-20, 25, 31-32, 34-38, and 40-43 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Pallikaris et al. (US 7,004,953) in view of Foggia et al. (US 5,782,852). Claims 9 and 21 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Pallikaris/Foggia in view of Samuels (US 6,247,389). Claims 10, 12, 22, and 24 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Pallikaris/Foggia in view of Feingold (US 6,083,236). And Claims 11 and 23 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Pallikaris/Foggia in view of Scwemberger et al (US 5,569,292). The Applicant respectfully traverses the grounds of these rejections.

Admittedly, it is established law that using one known material instead of another one to make a known machine is usually within the competence of those of ordinary skill in the art. However, it is also established law that if by the use of the different known material the machine or process acquires or produces some new and useful result, function, and/or property, such as increased efficiency or operational savings, then "it may be patentable as an invention, though the only change made in the machine has been supplanting one of its materials by another." *Smith v. Goodyear Dental Vulcanite Co.*, 93 US 486, 496 (1877). In *Smith*, the invention resided in making artificial teeth of a known material, vulcanite (i.e.,

hard rubber), instead of other known materials. *Id.* The Supreme Court found that this produced new and useful results, functions, and/or properties, in particular:

a set of artificial teeth, light and elastic, easily adapted to the contour of the mouth, flexible, yet firm and strong, consisting of one piece, with no crevices between the teeth and the plate, impervious to the fluids of the mouth, unaffected by the chemical action to which artificial teeth and plates are subjected when in place, clean and healthy, peculiarities which distinguish it from every thing that had preceded it. *Id.*

Based on this finding, the Supreme Court held that the claims of the patent at issue were non-obvious and valid.

Similarly, the invention of independent Claims 1, 14, 21, and 31 all recite the use of a polymer in a separator of a surgical device for laser refractive eye surgery. Laser refractive eye surgery has been around for a few decades, and the only types of blade that are known to have been used for forming the corneal flap (so the lens beneath the corneal flap can be ablated) are extremely sharp and expensive precision metal blades. The use of a polymer to make a blunt separator for use in laser refractive eye surgery is a radical departure from this. This innovation produces a separator that in use peels back corneal epithelium from corneal Bowman's layer without cutting into the Bowman's layer so that the corneal Bowman's layer is not incised or otherwise damaged, that is disposable and thus safer because of the decreased risk of contamination from previous uses, and that produces cost savings for the patient and surgeon. Because of these new and useful characteristics, the use of a polymeric material in a separator of a surgical device for laser refractive eye surgery is believed to be non-obvious and therefore patentable.

In addition, there are secondary considerations that support the patentability of the invention of Claims 1, 14, 21, and 31. First, making extremely precise incisions in the human eye is an entirely different thing from cutting a finger, and the cited references

therefore actually teach away from using plastic to make microkeratome blades for laser refractive eye surgery due to the precision required. Second, there are different design criteria for microkeratome blades for laser refractive eye surgery and blades for cutting fingers, for example, cost is not so much of an issue, while safety and precision are, etc. Third, there is a long-felt need for the claimed invention, because it solves the problems from laser refractive eye surgery related to cutting into the Bowman's layer, risk of contamination from previous blade uses, and high costs. For these additional reasons, Claims 1, 14, 21, and 31 are believed to be patentable.

Furthermore, the Applicant requests reconsideration of its position that the Foggia reference is not pertinent art. The Foggia reference discloses a finger-sticking device for creating a puncture wound from which a blood sample can be obtained. The surgical arts is a vast multidisciplinary field with many quite highly specialized areas. The specialized field of refractive eye surgery includes many highly specialized devices, including sophisticated, extremely expensive lasers systems and microkeratomes. A designer pursuing safer and more precise designs in blades for microkeratomes for use in refractive eye surgery would not reasonably be expected to investigate finger-sticking devices. Because finger-sticking devices are so far afield from microkeratomes for laser refractive eye surgery, a person of ordinary skill in the art designing advanced microkeratomes would not look to the field of finger-sticking devices for guidance. For this reason, the Applicant respectfully asserts that the Foggia reference is not pertinent art, and requests this rejection be withdrawn.

For all of these reasons, the Applicant respectfully asserts that independent Claims 1, 14, 21, and 31 are patentable over the cited references. Claims 1, 3-13, 15-20, 22-25, 32, 34-38, and 40-43 all depend from Claims 1, 14, and 31, so these dependent claims are also believed to be in condition for allowance.

In addition, independent Claim 21 is rejected based in part on the Samuels reference. The Samuels reference discloses polymer cutters that cut polymer strands. This reference is wholly unrelated to microkeratomes for laser refractive eye surgery. Quite simply, a person of ordinary skill in the art designing advanced microkeratomes would not look to the field of polymer-strand-cutting devices for guidance.

For this additional reason, the Applicant respectfully asserts that the Samuels reference is not pertinent art, and requests this rejection be withdrawn. Claims 22-25 all depend from Claim 21, which is believed to be in condition for allowance for the reasons set forth above. So these dependent claims are also believed to be in condition for allowance.

Furthermore, Claim 31 as amended recites the step of *disposing of the separator after a single use*. None of the cited references disclose using a blunt polymeric separator to separate the epithelium from the cornea, leaving Bowman's layer intact, and then disposing of the separator after a single use. All known microkeratomes have very expensive metal blades that are sanitized and reused. It is not known for surgeons to re-use these blades, as doing so would be cost-prohibitive. Because none of the cited references disclose, teach, or suggest the claimed steps, the Applicant requests that this rejection be withdrawn.

For this additional reason, Claim 31 is believed to be in condition for allowance. Claims 32, 34-38, and 40-43 depend from Claim 31, so these claims are also believed to be in condition for allowance.

CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, the Applicant respectfully requests early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone the Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,

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